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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,221	08/08/2003	Randall M. Smith	9226-99144-US	3334
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EXAMINER LAURITZEN, AMANDA L				
ART UNIT		PAPER NUMBER		
3737				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/637,221

Applicant(s)

SMITH ET AL.

Examiner

AMANDA LAURITZEN

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 48-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the panel decision from pre-appeal brief review dated 11 March 2011, stating that prosecution is to be reopened based on the difference in the claims specifying a microwave source, as discussed in the examiner interview on 14 September 2010. The Office action dated 21 June 2010 has been withdrawn. Upon further consideration, new grounds of rejection are presented in view of Gleman (US 2005/0251018), as applicable to the amendment filed 05 May 2010.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 28, 41 and 46 recite “a predefined microwave waveform,” but applicant’s disclosure is not specific to the details of the waveform or that it is predefined or in which way(s) it is predefined. Examiner therefore concludes that applicants fail to provide support for the limitation, “predefined microwave waveform” including any variation(s) on that wording. Additionally, claim 41 states that reflected energy is used from each breast independently;

however, this feature is also absent from applicant's specification and cannot be inferred from anything disclosed or depicted in the figures and therefore applicant fails to provide support for this feature as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2.1 Claims 1, 2, 6, 7, 9, 10, 17-20, 21, 24-38, 41-46 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleman (US 2005/0251018) in view of Carr (US 5,983,124).

Gleman discloses a radio-frequency imaging method and associated imaging system comprising a source and detector that operates under a very broad range of frequencies, "including all the standard RF bands from VLF [very low frequency] to microwaves..." as in

[0012]. An exemplary experiment with the system is described at [0058]-[0059], in which microwave energy is the target frequency range, which is understood to be transmitted from a source (RF source 20) in a predefined waveform. Detectors are configured to receive the microwave energy and process it for visualization of internal tissue structures, including cancerous tissues, as in [0012]. For these reasons, the apparatus of Gleman is capable of detecting and/or visualizing breast lesions, with examination of breast tissue.

Gleman does not disclose specifics regarding the examination table, save for the fact that a table is provided, as in [0059]. Gleman also does not specifically detail a patient support apparatus or an orientation system. In a similar field of microwave image generation, Carr teaches an apparatus and associated method for screening or diagnosing cancer in the breast of a patient comprising a support system for supporting the patient's breast in a fixed position with an orientation system for orienting the surface of the breast in known positions with respect to the anatomy of the patient and locations of the receive antenna. See, for example, the microwave-transparent padding scan plate as shown in Figs. 1 and 6 that enables orientation of the breast in known positions relative to position indicia and with respect to both the patient anatomy and antenna(e) located within the probe, as in col. 4, lines 20-35; col. 5, lines 10-35; col. 9, lines 43-60; also col. 2, line 61 – col. 3, line 10, in which positioning is with respect to antenna(e). It would have been obvious to one ordinarily skilled in the art at the time of invention to provide the active microwave imaging assembly of Gleman with the microwave-transparent patient-supporting apparatus of Carr, in order to better target specific tissue sites for diagnosis. The foam pads of Carr are comprised of thermally insulating material and are therefore padded to some degree and contoured for comfort, as in col. 9, lines 25-42 and shown in Fig. 6. The

insulating pads dually function as a gridded orientation system that is pressed in contact with the breast, as shown in Fig. 6 and disclosed at col. 9, lines 43-60. It would have been obvious to one ordinarily skilled in the art at the time of invention to modify the active microwave imaging system of Gleman with the microwave-transparent patient-supporting and orienting structure of Carr, in order to better receive the patient for targeted imaging of specific tissues. Regarding claim 25, the support member is taken to be the grid/scan plate (of Figs. 1 and 6) of the Carr reference and it is understood to be modular and therefore removable from the system.

Neither Gleman nor Carr is specific to providing a patient in a prone position on a table; however, it would have been obvious to one ordinarily skilled in the art at the time of invention to modify the supine positioning of the patient in the method of Carr to include prone imaging position(s), such that a breast is able to be positioned above the microwave-transparent scan plate of Fig. 1 (Carr) rather than below, as it is known to skilled artisans to position patients in any of a number of positions for breast imaging scans, including both prone and supine positions. Modifying the combination of Gleman and Carr for prone patient positioning is a simple rearrangement of parts, as the method steps and technologies employed are applicable regardless of the orientation of the patient. Since examiner finds that there are no structural limitation(s) that specifically require prone positioning, and the orientation apparatus and patient table could be easily modified to enable prone or supine patient positioning, this feature is not interpreted to define around the prior art. Both supine and prone patient positioning have well-documented advantages within the field of patient imaging; for example, it is understood that the relative comfort of the patient is enhanced with apparatuses that accommodate positioning in the prone position.

Regarding claim 7, Carr discloses a microwave-transparent scan plate (shown in Figs. 1 and 6) but does not disclose the dielectric constant of the plate to be within the range of 1.7-9; however other materials of the apparatus are disclosed within that range (e.g., the probe at col. 8, lines 46-54). Because the plate is microwave-transparent and appropriate for imaging, it is understood that this component of the apparatus is also within this dielectric range.

Regarding claim 10, Examiner understands an air gap of less than 3 mm to be provided between the antenna and scan plate of the apparatus of Carr as the antenna is disclosed to make intimate contact (col. 5, lines 32-35), which is most broadly interpreted to encompass close proximity and/or material touching.

Regarding claim 21, neither Gleman nor Carr expressly disclose digital camera viewing means, but at least Gleman is specific to display of digital images (which, as broadly interpreted, as permissible, would come from a digital camera source, with a modality not otherwise specified). It additionally would have been obvious to one ordinarily skilled in the art to provide convenient and flexible imaging acquisition, processing and viewing with a digital camera system (specific) as claimed. Additionally, providing a digital camera system allows for external anatomical imaging that serves to supplement the digital microwave images.

2.2 Claims 3-5, 8, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleman and Carr, as applied to claim 2 above, further in view of Meaney et al. (US 2004/0077943).

The combination of Gleman and Carr includes all limitations of the invention as substantially claimed including examination of the armpit area (auxillary gland at col. 2, line 65)

and as detailed above, but does not disclose incorporating an optical camera in the microwave imaging system; however, in the same field of microwave array imaging, Meaney et al. teach acquiring optical images that are to be overlaid with the microwave scan images (par. 14, in which microwave images are “spatially co-registered” with a 3-D optical image; see also claim 70 for overlaying with a 3-D optical image). It would have been obvious to one of ordinary skill in the art at the time of invention to combine the optical imaging system with the microwave imaging system as taught by Meaney for the purpose of corresponding microwave-detected internal abnormalities with a specific visual reference of the breast exterior (for motivation, see par. 54 of Meaney et al).

Regarding claim 21, neither Gleman, Carr nor Meaney expressly disclose digital camera viewing means, but it would have been obvious to provide a digital camera for the optical imaging means disclosed with the microwave/optical imaging system of Meaney as digital imaging systems are well known in the art to provide convenience and flexibility for image acquisition, processing, and viewing.

Regarding claim 22, the antenna contained within the probe of Carr is disclosed to move along coordinates (refer to Fig. 6 for coordinate grid; see also col. 9, lines 43-60), but this movement is not disclosed as provided by a motorized system; however, movement of the antenna disclosed by Meaney is provided with an actuator/drive shaft (paras. 12-13). Since movement of the antenna of Meaney does not require physical placement on the part of the medical examiner, the drive shaft inherently includes some sort of motorized system (additionally, a motor is a simple means of actuation that is well known in the art). It would have been obvious to include a motorized actuator as described by Meaney for movement of the

antenna along coordinates, as disclosed by Carr for the modification of Gleman, in order to enhance accuracy and precision by automating placement of the probe.

2.3 Claims 11, 12, 13-16, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleman and Carr, further in view of Haddad et al. (US 6,454,711).

The combination of Gleman and Carr includes all features of the invention as substantially claimed but does not include microwave absorbing material, but in the same field of endeavor Haddad et al. disclose microwave absorbing material (col. 3, line 27). It would have been obvious to incorporate use of a microwave absorbing material for the purpose of reducing residual crosstalk between the antennas of the apparatus of Carr as modifying Gleman (for motivation, see Haddad col. 3, lines 27-28).

2.4 Claim 23 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleman in view of Carr, further in view of Horton et al. (US 5,168,514).

The combination of Gleman and Carr includes all features of the invention as substantially claimed but does not include an adjustable upper surface section of the examination table that enables the patient to sit in an upright position; however, Horton et al. disclose adjustable back-rests and other surfaces as part of an examination table that provide a patient with support in a seated position while undergoing medical procedures in which breast tissue is targeted (col. 2, lines 44-47). It would have been obvious to one of ordinary skill in the art to provide the breast examination table of Carr, as used to modify the system of Gleman, with

adjustable support members disclosed by Horton in order to position the patient such that the targeted anatomy is fully accessible to the medical examiner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA LAURITZEN whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
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3737

